

Serial No.: 10/766,139  
Docket No.: PVI-5541DIVCON  
Amendment dated June 28, 2006  
Responsive to the Office Action dated May 11, 2006

### **REMARKS**

By way of this amendment, Applicant has canceled claims 23 and 27-37, and has added claims 38-49. Therefore, claims 18-22, 24-26, and 38-49 remain pending. Applicant has amended claim 18 to further clarify preferred features of the claimed invention.

### **Restriction Requirement**

The claims were subject to a Restriction Requirement between the following two inventions:

- I. Claims 18-28, drawn to a heart valve, classified in class 623, subclass 2.1;
- II. Claims 29-37, drawn to a method of implantation, classified in class 623, subclass 902.

During a telephone conversation with Applicant's representative on April 13, 2006, a provisional election was made to prosecute the claims in Group I. In this response, Applicant affirms the election of Group I without traverse. As a result, method claims 29-37 have been canceled.

### **Claim Rejections - 35 U.S.C. §112**

Claims 23 and 27-28 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response to the rejection, Applicant has canceled claims 23 and 27-28 and the limitations of claim 23 have been incorporated into claim 18. The terminology suggested by the Examiner has been incorporated into the language of claim 18. Applicant would like to thank the Examiner for providing suggestions regarding how to correct the language of the claims.

Serial No.: 10/766,139  
Docket No.: PVI-5541DIVCON  
Amendment dated June 28, 2006  
Responsive to the Office Action dated May 11, 2006

**Rejection of Claims 18-22 and 24-28 under 35 U.S.C. §102(e)**

Claims 18-22 and 24-28 stand rejected under 35 U.S.C. §102(e) as being anticipated by Garrison et al. (USPN 6,425,916). As noted above, independent claim 18 has been amended to include the limitations of claim 23. As a result, the rejection of claims 18-22 and 24-28 under 35 U.S.C. §102(e) as being anticipated by Garrison et al. have been rendered moot. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejections of claim 18-22 and 24-28 as being anticipated by Garrison et al. under 35 U.S.C. §102(e).

**Rejection of Claims 18-24 under 35 U.S.C. §102(e)**

Claims 18-24 stand rejected under 35 U.S.C. §102(e) as being anticipated by Eberhardt (USPN 6,350,282). The Examiner asserts that Eberhardt discloses an expandable valve "because the base is made of a flexible material, it is capable of being flexed, folded, etc., therefore it is expandable." Applicant respectfully disagrees with the Examiner's characterization of the cited reference. Eberhardt fails to teach or suggest a heart valve that is "expandable from a collapsed state to an expanded state," as recited by Applicant in claim 18. The mere fact that Eberhardt contemplates a flexible material is not sufficient to suggest that Eberhardt has disclosed an expandable valve.

To more explicitly distinguish the claimed invention over Eberhardt, Applicant has amended claim 18 to specify the relative sizes of the collapsed state and the expanded state. More particularly, claim 18 now recites "a substantially cylindrical tissue-engaging base portion expandable from a collapsed state to an expanded state, the collapsed state sized for delivery through a delivery catheter to a heart valve annulus and the expanded state sized to contact the heart valve annulus."

Furthermore, Applicant notes that claim 18 specifies a two-part prosthetic heart valve with a tissue-engaging base and a leaflet subassembly attachable thereto. To clarify the structure, Applicant has also amended claim 18 to recite that "the leaflet subassembly is configured to mechanically connect to the tissue-engaging base portion for providing a prosthetic heart valve."

Serial No.: 10/766,139  
Docket No.: PVI-5541DIVCON  
Amendment dated June 28, 2006  
Responsive to the Office Action dated May 11, 2006

In contrast, Eberhardt merely discloses a suturing cuff (54) integrally formed with the rest of the heart valve. Eberhardt does not disclose or suggest a two-part structure including a leaflet subassembly configured to mechanically connect to the tissue-engaging base portion for providing a prosthetic heart valve.

Therefore, Eberhardt fails to anticipate claims 18-24 under 35 U.S.C. §102(e). Accordingly, Applicant respectfully requests the Examiner to withdraw the rejections of claim 18-24 as being anticipated by Eberhardt under 35 U.S.C. §102(e).

**Rejection of Claims 18-24 and 26 under 35 U.S.C. §102(e)**

Claims 18-24 and 26 stand rejected under 35 U.S.C. §102(e) as being anticipated by Carpentier et al. (USPN 6,558,418). The Examiner asserts that Carpentier et al. disclose an expandable valve "because the base is made of a flexible material, it is capable of being flexed, folded, etc., therefore it is expandable." Applicant respectfully disagrees with the Examiner's characterization of the cited reference. Carpentier et al. fail to teach or suggest a heart valve that is "expandable from a collapsed state to an expanded state," as recited by Applicant in claim 18. The mere fact that Carpentier et al. contemplate a flexible material is not sufficient to suggest that Carpentier et al. have disclosed an expandable valve.

As discussed above, Applicant has amended claim 18 to recite "a substantially cylindrical tissue-engaging base portion expandable from a collapsed state to an expanded state, the collapsed state sized for delivery through a delivery catheter to a heart valve annulus and the expanded state sized to contact the heart valve annulus." Carpentier et al. neither disclose nor suggest a substantially cylindrical tissue-engaging base portion. Furthermore, Carpentier et al. neither disclose nor suggest a base portion having a collapsed state sized for delivery through a delivery catheter. Rather, Carpentier et al. merely disclose a surgically implanted prosthetic heart valve formed from a connecting band (48) and inner stent (70) wherein, after implantation, the structure has sufficient flexibility to follow the aortic wall motion during systole and diastole phases of the heart.

Serial No.: 10/766,139  
Docket No.: PVI-5541DIVCON  
Amendment dated June 28, 2006  
Responsive to the Office Action dated May 11, 2006

Therefore, Carpentier et al. fail to anticipate claims 18-24 and 26 under 35 U.S.C. §102(e). Accordingly, Applicant respectfully requests the Examiner to withdraw the rejections of claim 18-24 and 26 as being anticipated by Carpentier et al. under 35 U.S.C. §102(e).

### New Claims

Applicant has added new claims 38-49 to recite additional preferred features of the present invention.

Claim 38 provides a two-part prosthetic heart valve having an expandable tissue-engaging base, a leaflet subassembly including a support structure and three heart valve leaflets, and a plurality of discrete mating connectors on the leaflet subassembly and tissue-engaging base, wherein the mating connectors are configured to mechanically couple the leaflet subassembly to the tissue-engaging base when the tissue-engaging base is in the expanded state. None of the cited reference discloses or suggests a two-part valve having the features of claim 38. More particularly, none of the cited references discloses or suggests anything about a plurality of discrete mating connectors for coupling the leaflet subassembly to the tissue-engaging base. For example, Garrison et al. merely disclose a valve displacer (8) and a cardiac valve (6) that is configured for expansion within the valve displacer. In another distinguishing feature, Applicant notes that neither Eberhardt nor Carpentier et al. discloses or suggests a tissue-engaging base that has a collapsed state sized for advancement through a patient's vasculature to a heart valve annulus. Rather, Eberhardt and Carpentier et al. each disclose prosthetic heart valves configured for surgical deployment.

Claim 44 provides a two-part prosthetic heart valve with a tissue-engaging base expandable from a collapsed state sized for advancement through a delivery catheter to an expanded state sized to contact the valve annulus, the tissue-engaging base generally defining a tubular body having an inflow end and an outflow end; and a leaflet subassembly including three heart valve leaflets that is configured to mechanically couple to the tissue-engaging base. The tissue engaging base and leaflet subassembly are configured such that, after assembly, the three

Serial No.: 10/766,139  
Docket No.: PVI-5541DIVCON  
Amendment dated June 28, 2006  
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heart valve leaflets are axially spaced from the outflow end of the tubular body such that the heart valve leaflets are not positioned within the tubular body. In other words, the heart valve leaflets are preferably positioned outside (i.e., downstream) of the tissue-engaging base at a location adjacent the outflow end of the tissue-engaging base. None of the cited references discloses a valve having these features.

Accordingly, Applicant respectfully asserts that new claims 38 and 44 and the claims which depend thereon are in condition for allowance.

**Fees Due to File This Amendment**

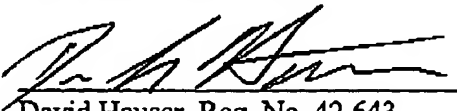
Prior to the pending Office Action, a fee was paid for the original 20 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

**CONCLUSION**

Should the Examiner have any questions, the Examiner is encouraged to contact the attorney of record at the telephone number indicated below.

Respectfully submitted,

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